OCT 19 2010

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,740,522 was filed on July 27, 2010, under 35 U.S.C. § 156. Please note that Applicant has also applied for patent term extension for U.S. Patent No. 7,097,834; U.S. Patent No. 7,411,050, U.S. Patent No. 7,449,185, and U.S. Patent No. 7,527,790 pursuant to 37 C.F.R. § 1.785, for BLA No. 125320 licensed on June 1, 2010.

The assistance of your Office is requested in confirming that the product identified in the application, PROLIA® (denosumab), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
 for Patent Examination Policy

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